REMARKS

Interview Summary

An interview in reference to this application was held by telephone on December 8, 2009. In attendance was Examiner Nathan Schlientz, inventor Stephen A. Mamchur, and applicant's representatives Robert M. Gamson and Michael Schiff.

The claim rejections under 35 USC §§ 102 and 103 were discussed. Applicant and his representatives proposed some claim amendments and an expert declaration that would further explain how the prior invention differed from anything taught or suggested in the cited references.

Applicant is grateful to the Examiner for his kind and thoughtful consideration of the matters under discussion. The wording of several of the claims presented here has been changed from the amended claims proposed during the interview, in view of the Examiner's concerns, and applicant's current commercial interests.

The application is believed to be in condition for allowance, which is respectfully requested.

Claim amendments

The amendments to the claims presented in this Response provide additional features to the claims as previously presented. Claims 124, 136, and 138 are newly cancelled. No new claims have been added.

Support for the amendments is derived from the claims as previously presented. Claim 123 incorporates features previously presented in dependent claim 124. Claims 125 and 135 have been rewritten as independent claims, and incorporate limitations previously appearing in claims 123 and 132 respectively. Reference to equal volumes of ethoxy diglycol and propylene glycol in claims 125 and 132 is supported *inter alia* in Example 6 (paragraph [0249] of US 2004/0180866) which refers to making the volume of a liquid product up to a final amount using a 50:50 mixture of ethoxy diglycol and propylene glycol.

The claim amendments place the application in better condition for allowance or appeal. Accordingly, entry of the claims into the application pursuant to 37 CFR § 1.116 is requested.

Objections and Rejections under 35 USC § 112

Claim 146 is objected to and claims 123 and 125 stand rejected under § 112 ¶ 2 for reasons related to claim wording. These matters have been addressed in the claim amendments provided here.

Rejections under 35 USC §§ 102 and 103

All the claims previously pending in the application stand rejected as lacking novelty or being obvious over previously published patents and applications by Chiang (WO 90/11064), Rosenbaum (U.S. Patent 5,709,878), Carrara (WO 02/11768), and Muni (U.S. Patent 6,708,822), either alone or in combination. Applicant respectfully disagrees.

Enclosed with this Response is an expert Declaration under 37 CFR § 1.132 by the inventor. Dr. Mamchur explains the following points:

- Dr. Mamchur developed his system of concentrated hormone reagent compositions to allow ordinary retail pharmacists to make pharmaceuticals that are custom tailored to the needs of each individual consumer.

- The Chiang, Rosenbaum, and Carrara references are focused on providing final products, not reagent systems.

- The Muni patent provides a kit that is intended for batch production of off-the-shelf products. A single component containing the active agent is combined with a single component which contains the excipient at a standardized ratio.

- The working examples currently sold by *Cutispharma,* the owners of the Muni patent, confirm that the Muni technology is designed for batch production. [The single mention of "individualized therapy" referred to in the Muni patent means only that different kits can provide different dosages of off-the-shelf products.]

- The Muni patent does not teach solutions containing a combination of estrogens. The estrogen combinations referred to in the patent are provided in solid form with lactose as a filler.

- None of the references suggest that active ingredients should be prepared as concentrated reagents, and then measured out in different amounts for each consumer — as claimed in the present application.

- None of the references suggest that a plurality of concentrated reagents containing different hormones can be combined together based on a consumer's particular needs — as claimed in the present application.

- Dr. Mamchur's system of concentrated reagents provides a new and effective way to address a therapeutic need that has become increasingly recognized.

- Dr. Mamchur's system has won awards in entrepreneur competitions. [This verifies both the originality and commercial importance of the claimed invention. MPEP § 2145].

The claims as amended in this Response provide a number of distinguishing features from the cited references.

Claim 123 and its dependents refer to steroid hormones dissolved in a solvent mixture consisting of ethoxy diglycol and propylene glycol. Claim 125, 132 and their dependents refer to a solution comprising concentrated estrogen(s) and equal volumes of ethoxy diglycol and propylene glycol. None of the references teach or suggest making hormone solutions where ethoxy diglycol and propylene glycol are used together as the primary solvents.

Claim 135 and its dependents refer to a reagent solution for preparing pharmaceuticals that contains a combination of three particular estrogens dissolved at high concentration. None of the cited references teach or suggest this combination of estrogens in a concentrated reagent solution.

Claim 141 and its dependents refer to a compounding system having several different hormone reagent solutions that are so concentrated that they can be combined with other hormone reagent solutions to provide an effective level of several different hormones in the final product. Claim 160 and its dependents refer to the use of concentrated hormone reagent solutions to make pharmaceutical products that are custom tailored for each consumer. As explained in Dr. Mamchur's Declaration, none of the cited references teach or suggest the combining of more than one reagent solutions containing different hormones to make a pharmaceutical product of any kind. None of the cited references teach or suggest a system that allows reagents to be combined in such a way to produce pharmaceutical products that are each tailored for the needs of different consumers.

Thus, all the claims currently presented are novel with respect to each of the references. The Muni patent cannot be combined with the other references under § 103 as proposed in the Office Action, because they have different objects (MPEP § 2143.01(VI)): specifically, Muni is focused on providing kits of solids and/or liquids that can be combined by the user, whereas the other references are focused on the manufacture of end-stage products with particular penetration enhancers. Nevertheless, even when combined, the references do not teach or suggest all the features of the claims as currently presented.

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

Request for interview

In the event that the Examiner determines that there are other matters to be addressed, applicant and his representatives hereby request a further interview by telephone.

Respectfully submitted,

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Date

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